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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,209	11/16/2001	Nigel Dunn-Coleman	GC648-2	6062

5100 7590 03/09/2005

GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/991,209

Applicant(s)

DUNN-COLEMAN ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12,14,15,18,19,23,25,27-33 and 74-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12,14,15,18,19,23,25,27-33 and 74-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/2005 has been entered.

Claims 1-12, 14-15, 18-19, 23, 25, 27-33 and 74-79 are pending and examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection of claims 2, 8, 14, 25, 27-29 and 74 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments.

### ***Claim Rejections - 35 USC § 112***

Claims 1-12, 14-15, 18-19, 23, 25, 27-33 and 74 remain and new Claims 75-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04 and 11/03/2004. Applicant's arguments filed 8/16/04 and 2/18/2005 have been fully considered but they are not persuasive.

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Applicant asserts that one of skill in the art could isolate ferulic acid esterases and that many were known in the art (response page 8 lines 20-27). Although isolates from various fungal organisms have demonstrated FAE activity their enzymatic sequences have not been described. Moreover, Applicant's remarks that many were known in the art is contrary to Applicant's teaching on page 16 of the specification that only one FAE gene has been cloned. U.S. Patent 6,368,833 does not describe multiple ferulic acid enzymes it teaches isolation of one polynucleotide encoding one ferulic acid esterase enzyme isolated from *Aspergillus* (See Abstract). Although each and every embodiment need not be described, from Applicant's lack of written description of the claimed genus it remains unclear what features identify a ferulic acid esterase encoding polynucleotide.

Claims 1-12, 14-15, 18-19, 23, 25, 27-33 and 74 remain and new Claims 75-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic *Festuca* and *Lolium* comprising a polynucleotide encoding an FAE1 enzyme from *Aspergillus* of SEQ ID NO: 1 wherein expression of the *Aspergillus* FAE1 is targeted to the vacuole, ER, or apoplast, does not reasonably provide enablement for any grass plant comprising any FAE1 encoding polynucleotide from any organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04 and 11/03/2004. Applicant's arguments filed 8/16/04 and 2/18/2005 have been fully considered but they are not persuasive.

Applicant asserts since a ferulic acid esterase may be isolated using the methods of U.S. Patent 6,368,833 and given the teachings of the specification each and every embodiment of the specification could be isolated (response page 8 lines 20-27). Applicant further asserts, “that while a fair amount of experimentation may be required this experimentation would be routine and not undue experimentation” (response page 8, lines 25-27). However unpredictability would transform the “routine experimentation” into undue trial and error experimentation. The unpredictability of identifying a ferulic acid esterase encoding polynucleotide that should have activity in a plant is illustrated in experiments where a polynucleotide believed to encode a ferulic acid esterase showed no activity towards an esterified ferulic acid (Kroon P. *et al.* Biochemical Society Transactions, 1998; Vol. 26; page S167, column 2, second paragraph; previously presented). Moreover, ferulic acid esterase activity i.e. substrate specificity can vary greatly. For example, the ferulic acid esterase encoding polynucleotide isolated from *Aspergillus niger* showed activity for ferulic acid esterified to C5 of arabinofuranose found in cereals and grasses but showed no activity towards ferulic acid esterified to the C2 and C6 residues of arabinofuranse and galactopyranose residues respectively, typical of esterified ferulic acid found in sugar beet. Also, see *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a “mere germ of an idea does not constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Given the unpredictability in the art as to which ferulic acid esterase encoding polynucleotides would have activity upon a conjugated ferulic acid substrate associated with a particular plant species; the breadth of the claims encompassing any ferulic acid esterase

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encoding polynucleotide; the lack of guidance in the examples of the specification or in the prior art; undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified ferulic acid esterase encoding polynucleotides and would require one of skill in the art to test in a myriad of non-exemplified grass plants for an altered phenotype in a multitude of non-exemplified transformed plant grass species. Therefore, the invention is not enabled for the scope set forth in the claims.

***Claim Rejections - 35 USC § 102***

Claims 1-2, 8, 14 and 23 remain rejected under 35 U.S.C. 102(a) as being anticipated by Michelson B. *et al.* U.S. Patent 6,143,543 issued November 7, 2000. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04. Applicant's arguments filed 8/16/04 have been fully considered but they are not persuasive. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04 and 11/03/2004. Applicant's arguments filed 8/16/04 and 2/18/2005 have been fully considered but they are not persuasive.

Applicants asserts that the teachings of Michelson are not enabling for production of an FAE enzyme in a plant and secreted there from because there is no teaching of how this might be accomplished (response page 9 lines 17-19) and that this could be used for improving the digestability of the plant because of the 'improved cell wall structure' (response page 9 lines 22-24). In response to Applicant's arguments that production of an FAE enzyme in a transformed plant could be used for improving the digestability of the plant because of the 'improved cell wall structure' or 'to achieve cell wall modification' is not a teaching of the '543 Patent reference and therefore does not anticipate the claimed invention, a recitation of the intended use

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of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The *Aspergillus* sequence of the '543 Patent, known in the art, inherently teaches a signal sequence; see the first non-patent publication listed in references cited, de Vries *et al.*, on page 4640 column 2. Further, there is no evidence to suggest that the FAE and the techniques taught in the specification of Michelson would not result in the stable expression of FAE in a transformed plant.

***Claim Rejections - 35 USC § 103***

Claims 1-2, 8-12, 14, 23, 25, 27-29, 31 and 74 remain and new Claims 75 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson *et al.* U.S. Patent 6,143,543 issued November 7, 2000 in view of Bartolome B. *et al.*, Applied and Environmental Microbiology; January 1997, pages 208-212. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04 and 11/03/2004. Applicant's arguments filed 8/16/04 and 2/18/2005 have been fully considered but they are not persuasive.

Applicant asserts that the '543 Patent fails to teach all the elements of the invention and that there is no reasonable expectation of success (response page 10, lines 19-21). Michelson provides motivation to transform a grass plant with an FAE encoding polynucleotide by teaching a plant comprising an expression cassette comprising a ferulic acid esterase encoding polynucleotide derived from *Aspergillus niger*, operably linked to a promoter, taught as an

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embodiment of the invention and provides a reasonable expectation of success by teaching that the recombinant FAE and xylanase together released ferulic acid and diferulate dimers from cell walls of wheat.

Applicant asserts that there is no teaching of targeting FAE expression to cell walls to improve cell wall structure (response page 10, lines 21-22). In response to Applicant's arguments that production of an FAE enzyme in a transformed plant could be used for improving the digestability of the plant because of the 'improved cell wall structure' or 'to achieve cell wall modification' is not a teaching of the '543 Patent reference and therefore does not anticipate the claimed invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The *Aspergillus* sequence of the '543 Patent, known in the art, inherently teaches a signal sequence; see the first non-patent publication listed in references cited, de Vries *et al.*, on page 4640 column 2. Further, there is no evidence to suggest that the FAE and the techniques taught in the specification of Michelson would not result in the stable expression of FAE in a transformed plant.

Applicant asserts that there is no teaching suggesting a forage grass plant could be transformed with a DNA encoding an FAE polypeptide and an inducible promoter (response page 10, lines 22-24). Michelson provides motivation to transform a grass plant with an FAE



encoding polynucleotide by teaching a plant comprising an expression cassette comprising a ferulic acid esterase encoding polynucleotide derived from *Aspergillus niger*, operably linked to a promoter, taught as an embodiment of the invention and by teaching that the recombinant FAE and xylanase together released ferulic acid and diferulate dimers from cell walls of wheat.

Further, Applicant teaches that inducible and senescence promoters are well known in the art.

Applicant asserts that there is no teaching of how recombinant expression of an FAE in grass plants should be accomplished (response page 10, lines 29-31). Transformation of plants is provided by the '543 reference.

All claims are rejected.

Claims 3-7, 15, 18-19, 30, 32, 33 and 76 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest *Festuca*, *Lolium*, *Zea* and *Avena* plants transformed with ferulic acid esterase FAE1 from *Aspergillus* and xylanase from *Trichoderma reesei* encoding polynucleotides using an encoded signal sequence to target gene expression to the vacuole.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
March 3, 2005

A handwritten signature in black ink that reads "Russell Kallis". The signature is written in a cursive, flowing style.

**RUSSELL P. KALLIS, PH.D.  
PATENT EXAMINER**